

REMARKS

The Office Action mailed November 10, 2010 presents the examination of claims 1, 3, 4, 7-9 and 11-18. Claims 2, 5, 6 and 10 have been previously canceled.

This paper cancels claims 1-15 and 17-18 and amends claim 16. The amendment to claim 16 is supported by the specification at, e.g. the description of Figures 2-4 found at pages 13-14. The structure of the formula (I) is also corrected to replace the R group inadvertently omitted when claim 16 was added to the application. (*See, e.g.* formula (I) at page 5 of the specification). New claims 19-28 are added, which are based on the prior claims 3, 4, 7-9 and 17-18. A "sandwich" format for the competitive assay is described by the specification at page 15, lines 21-28.

Rejections under 35 USC § 112

Claims 1, 3 and 11-15 are rejected under 35 USC § 112, second paragraph, as allegedly being indefinite in omitting an "essential" step of separation of the two forms of vitamin D before assay for the $1\alpha,25$ dihydroxy form. The Examiner further considers the term "vitamin D binding protein" to be unclear as to whether or not it encompasses an antibody that specifically binds to $1\alpha,25$ dihydroxy vitamin D.

Claims 1, 3 and 11-13 are also rejected under 35 USC § 112, first paragraph, both for lack of lack of enablement of the claimed subject matter, also for failure of the claims to recite a step of separating the two forms of vitamin D prior to assay for the $1\alpha,25$ dihydroxy form.

Applicants disagree with the Examiner's assertions for all of the reasons set forth previously in the prosecution to date. Nonetheless, to advance the prosecution presently, the rejected claims are all canceled. Applicants have now arranged a set of claims around the prior claim 16, which includes the separation step the Examiner asserts is essential to the claimed method. The amended claims also do not use the term "vitamin D binding protein." Accordingly, the above rejections should be withdrawn.

Claims 1, 3 and 11-14 are rejected under 35 USC § 112, first paragraph for alleged lack of written description support for the claimed invention. The Examiner asserts that the specification fails to describe use of tracer 25-hydroxy vitamin D for the measurement of 1 α ,25 dihydroxy vitamin D in a sample and vice-versa, though these are encompassed by claim 1.

Notwithstanding that one of ordinary skill in the art would understand which tracers must be used to measure which analytes in the sample, the rejected claims have been canceled, rendering this rejection moot.

Claim 16 stands rejected under 35 USC § 112, first paragraph for alleged lack of written description support for the claimed invention. The Examiner asserts that the specification fails to describe that displacement of the compound of the formula (I) from an antibody that specifically binds to 1 α ,25 dihydroxy vitamin D with an efficiency of 1 is not described in the specification. This recitation has been deleted from claim 16, rendering this ground of rejection moot.

Rejections for obviousness

Claims 1, 3-4, 7-8 and 11 are rejected under 35 USC § 103(a) as being unpatentable over Holick WO '127. Claim 9 is rejected under the same statute as being unpatentable over Holick WO '127 in view of DeLuca '770. Claims 15, 17 and 18 are rejected under the same statute as being unpatentable over Holick WO '127 in view of Mawer 1985. The rejected claims are all canceled, rendering these rejections moot.

Obviousness-type double patenting

Claims 1-4, 7, 8 and 11-13 are rejected under the doctrine of obviousness-type double patenting over claims 1-5 of US 6787660. The rejected claims have all been canceled, rendering this rejection moot.

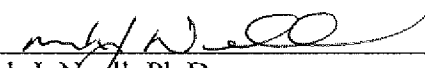
Applicants believe the pending application is in condition for allowance. The favorable actions of withdrawal of all standing rejections and allowance of the application are respectfully requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell, Ph.D., Reg. No. 36,623, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

By 
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